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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/814,982 | 03/30/2004 | Valery M. Dubin | 21058/0206743-US0 | 8631 |

75172 7590 02/05/2008

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| EXAMINER | |
|---|---|
| JUNG, UNSU | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 02/05/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/814,982 | DUBIN ET AL. | |
| | Examiner | Art Unit | |
| | Unsu Jung | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5,7-16,18-21 and 41-53* is/are pending in the application.

4a) Of the above claim(s) *5 and 41-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-16 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 August 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on October 29, 2007 has been entered. The submission included amendments to claims 1 and 14.

2. Claims 1-5, 7-16, 18-21, and 41-53 are pending, claims 5 and 41-53 have been withdrawn, and claims 1-4, 7-16, and 18-21 are under consideration for their merits.

It is noted that the status identifier of claim 5 indicates "Original" in the Listing of Claims in the reply filed on October 29, 2007. However, claim 5 has been withdrawn from consideration as a result of Restriction Requirement dated December 19, 2006. Therefore, the status of claim 5 should indicate "Withdrawn."

Typos are noted on the Office Action Summary (PTO-326) in the Office Action dated October 19, 2007. For pending and withdrawn claims, claims "41-43" should be corrected to "41-53."

***Rejections Withdrawn***

3. The following rejections have been withdrawn in view of amended claims 1 and 14 in the reply filed on October 29, 2007:

- Rejection of claims 14-16, and 19-21 under 35 U.S.C. 102(b) as being anticipated by Li (WO 02/031463 A2, Apr. 18, 2002);
- Rejection of claims 1-4, 7-12, 14-16, and 19-21 under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of Chazalviel et al. (*Applied Spectroscopy*, 1993, Vol. 47, pp1411-1416) and Yoshida et al. (JP 07-184883 A, July 25, 1995);
- Rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of Chazalviel et al. (*Applied Spectroscopy*, 1993, Vol. 47, pp1411-1416) and Yoshida et al. (JP 07-184883 A, July 25, 1995), and further in view of Dai et al. (U.S. Patent No. 6,528,020, Mar. 4, 2003); and
- Rejection of claim 18 under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of Ito (U.S. Patent No. 5,384,028, Jan. 24, 1995).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 14-16, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio et al. (WO 2004/001404 A1, published on December 31, 2003 and filed on June 19, 2003).

Li teaches an apparatus comprising a condensed array addressed device (see entire document, particularly p8) including a plurality of addressable cells (p8, Detailed Description of the Invention, 1st paragraph), each of the plurality of addressable cells including at least two electrodes (reference elements 1 and 5 in Fig. 2); and a spectroscope optically coupled to the condensed array addressed device (p34, last paragraph and p35).

With respect to claim 14, Li teaches that the plurality of addressable cells define a plurality of sensor elements configured as an array, wherein each of the sensor elements is functionalized to interact with one or more target molecules (p23, 2nd-7th paragraphs); and further comprising control circuitry coupled to the sensor elements, wherein the control circuitry is configured to detect interaction s of the sensors with the target molecules (p24, 4th paragraph).

With respect to claims 15-17, Li teaches the plurality of sensor elements configured as a two-dimensional high-density array (p39, 3td paragraph), which are addressable by corresponding rows and columns.

With respect to claim 19, Li teaches an apparatus, further comprising a microfluidic channel coupled to at least one of the addressable cells (p18, last paragraph and p19, 1st paragraph).

With respect to claims 20 and 21, Li teaches an apparatus, further comprising selective membranes (porous polymeric pads), which includes chemically and biologically selective membranes (p5, last paragraph).

Li further teaches that a variety of detection methods can be used with the condensed array addressed device including optical detection methods capable of detecting spectral changes upon changes in redox state including fluorescence, phosphorescence, luminescence, chemiluminescence, electrochemiluminescence, and refractive index detection methods. However, Li does not specifically teach that two different detection means, electrochemical and optical (spectroscope) detectors are coupled to the array device.

DeNuzzio et al. teaches microfabricated sensors with multiple working electrodes coupled to both optical and electrochemical detection means allowing the combination of the multiplexed electrochemical detection with optical detection in a single planar microcell (see entire document, particularly Abstract and p5, paragraph [0014]). The combination of various electrochemical, photometric, and other measurement results in a powerful analytical tool capable of measuring multiple properties of an analyte, as well as properties of multiple analytes simultaneously (p9, paragraph 0030]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ combination of both optical and electrochemical detectors of Li as taught by DeNuzzio et al. in order to allow combination of multiplexed electrochemical detection with optical detection in a single device. The advantage of allowing combination of multiplexed electrochemical detection with optical detection in a single device provides the motivation to combine teachings of Li and DeNuzzio et al. since the combination of various electrochemical, photometric, and other measurement results in a powerful analytical tool capable of measuring multiple properties of an

analyte, as well as properties of multiple analytes simultaneously. Further, one of ordinary skill in the art would have had a reasonable expectation of success in employing the combination of both optical and electrochemical detectors in the device of Li since DeNuzzio et al. teaches that simultaneous detection of both optical and electrochemical signals is possible with the combination of the multiplexed electrochemical detection with optical detection.

8. Claims 1-4, 7-12, 14-16, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio et al. (WO 2004/001404 A1, published on December 31, 2003 and filed on June 19, 2003), Chazalviel et al. (*Applied Spectroscopy*, 1993, Vol. 47, pp1411-1416), and Yoshida et al. (JP 07-184883 A, July 25, 1995).

Li teaches an apparatus comprising a condensed array addressed device (see entire document, particularly p8) including a plurality of addressable cells (p8, Detailed Description of the Invention, 1st paragraph), each of the plurality of addressable cells including at least two electrodes (reference elements 1 and 5 in Fig. 2); and a spectroscope optically coupled to the condensed array addressed device (p34, last paragraph and p35).

With respect to claims 8 and 9, Li teaches that the plurality of addressable cells includes an individually addressable cell, which includes a first individually addressable electrode and a second individually addressable electrode (p8, Detailed Description of the Invention, 1st paragraph).

With respect to claims 10-12, Li teaches that spacing between the electrodes is less than 1 μm (p17, 5th paragraph). Li further teaches that cross-dimensions of microchannels, in which the electrodes are located, is in the order of 0.1 to 500 μm (p19, 1st paragraph and Fig. 9C). Therefore, one of ordinary skill in the art would recognize that the electrodes located within the microchannels would have less than 100 nm in size.

Li further teaches that a variety of detection methods can be used with the condensed array addressed device including optical detection methods capable of detecting spectral changes upon changes in redox state including fluorescence, phosphorescence, luminescence, chemiluminescence, electrochemiluminescence, and refractive index detection methods. However, Li does not specifically teach that two different detection means, electrochemical and optical (spectroscope) detectors are coupled to the array device. Li further does not specifically teach an apparatus further comprising a waveguide, which includes a total internal reflection prism, wherein the spectroscope is optically coupled to the total internal reflection prism.

DeNuzzio et al. teaches microfabricated sensors with multiple working electrodes coupled to both optical and electrochemical detection means as set forth in item 7 above.

Chazalviel et al. teaches Fourier Transform (FT)-infrared (IR) spectroscopy, which is a well-known spectral detection method at the electrochemical interfaces (entire document, particularly p1416, *Conclusion*). The advantages of FT-IR spectroscopy are well known (p1416, *Conclusion*). The advantages include good

sensitivity and ability to smoothly extract varying contributions due to electronic absorptions and to obtain spectra as complex quantities, which is of considerable help in the identification of the vibration signals and in their ascription to one or the other of the many possible electrochemical processes (p1416, *Conclusion*).

Yoshida et al. teaches an optical system comprising FT-IR spectroscopy and an ATR (attenuated total internal reflection) prism, which provides infrared rays to infrared analysis equipment such as FT-IR spectroscopy (see entire translated document, particularly Abstract and paragraph [0005]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ combination of both optical and electrochemical detectors of Li as taught by DeNuzzio et al. in order to allow combination of multiplexed electrochemical detection with optical detection in a single device. The advantage of allowing combination of multiplexed electrochemical detection with optical detection in a single device provides the motivation to combine teachings of Li and DeNuzzio et al. since the combination of various electrochemical, photometric, and other measurement results in a powerful analytical tool capable of measuring multiple properties of an analyte, as well as properties of multiple analytes simultaneously. Further, one of ordinary skill in the art would have had a reasonable expectation of success in employing the combination of both optical and electrochemical detectors in the device of Li since DeNuzzio et al. teaches that simultaneous detection of both optical and electrochemical signals is possible with the combination of the multiplexed electrochemical detection with optical detection. Further, it would have been obvious to

one of ordinary skill in the art at the time of the invention to employ the FT-IR spectroscopy of Chazalviel et al. in the apparatus of Li in order to provide a spectral detection device at the electrochemical interfaces of the condensed array addressed device of Li for optical detection of biomoleclular interactions. The advantage of employing a sensitive detection device, which facilitates spectra information in complex quantities, provides the motivation to employ the FT-IR spectroscopy of Chazalviel et al. in the apparatus of Li with a reasonable expectation of success as the FT-IR spectroscopy is capable of smoothly extracting varying contributions due to electronic absorptions and the spectra in complex quantities is of considerable help in the identification of the vibration signals and in their ascription to one or the other of the many possible electrochemical processes. In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to select FT-IR spectroscopy as a detection system, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416. Because the claimed apparatus is known in the prior art and has been disclosed as being used with a spectroscope in general, the selection of a specific type of a spectroscope in itself does not present a novel feature of the claimed invention. Since one of ordinary skill in the art at the time of the invention would recognize that a plurality of different types of detection system can be used in the apparatus of Li for detection of biomolecular interactions based on same principle of detecting electrochemical species, it would have been obvious to employ a FT-IR spectroscopy as a detection system in the instant claims. Further, it

would have been obvious to further include a total internal reflection prism (waveguide), which is optically coupled to the FT-IR spectroscope as taught by Yoshida et al. in the apparatus of Li in view of Chazalviel et al. as it is generally known to use total internal reflection prisms in order to provide infrared rays to FT-IR spectroscope.

With respect to claim 4, the limitation of "the infrared spectroscope is electromodulated by applying potential between the at least two electrodes in at least one of the plurality of cells" is a recitation of the intended use of the claimed invention and must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The apparatus of Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al. meets all the structural limitation of claim 4 and would therefore be capable of performing the intended use limitation above. Further, Li teaches that a potential is applied between the two electrodes in the plurality of cells (p34, 4$^{th}$ paragraph).

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio et al. (WO 2004/001404 A1, published on December 31, 2003 and filed on June 19, 2003), Chazalviel et al. (*Applied Spectroscopy*, 1993, Vol. 47, pp1411-1416), and Yoshida et al. (JP 07-184883 A, July 25, 1995) as applied to claims 1 and 10 above, and further in view of Dai et al. (U.S. Patent No. 6,528,020, Mar. 4, 2003).

Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al. teaches an apparatus comprising a condensed array addressed device and an optically coupled spectroscope as set forth in item 8 above. Li further teaches that each of the pair of electrodes include carbon nanotubes (p23, 3rd paragraph). However, Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al. does not specifically teach that each of the pair of electrodes include single-walled carbon nanotubes or silicon nanowires.

Dai et al. teaches chemical/biological sensors comprising electrochemical nanotube devices, which demonstrate significant and robust response and more significantly tunable selectivity to chemical or biological species in their environments (see entire document). The nanotube is generally single-walled carbon nanotube or silicon nanotubes (nanowires, column 2, lines 21-27 and column 4, lines 17-22).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to specifically employ single-walled carbon nanotubes or silicon nanowires of Dai et al. as the nanotubes associated with the pair of electrodes of Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al. as it is well known that the electrochemical nanotube devices demonstrate significant and robust response and more significantly tunable selectivity to chemical or biological species in their environments. In addition, it would have been obvious to one of ordinary skill in the art at the time of the invention to select single-walled carbon nanotubes or silicon nanowires as a layer covering the electrodes of the condensed array addressed device, since it has been held to be within the general skill of a worker in the art to select a

known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416. Because the claimed apparatus is known in the prior art and has been disclosed as being capable of being used with carbon nanotubes in general, the selection of a specific type of a nanotube/nanowire in itself does not present a novel feature of the claimed invention. Since one of ordinary skill in the art at the time of the invention would recognize that a plurality of different types of nanotubes/nanowires can be used in the apparatus of Li in view of DeNuzzio et al., Chazalviel et al., and Yoshida et al. for detection of biomolecular interactions based on same principle of detecting electrochemical species, it would have been obvious to employ a single-walled carbon nanotubes or silicon nanowires in the instant claims.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li (WO 02/031463 A2, Apr. 18, 2002) in view of DeNuzzio et al. (WO 2004/001404 A1, published on December 31, 2003 and filed on June 19, 2003) as applied to claim 14 above, and further in view of Ito (U.S. Patent No. 5,384,028, Jan. 24, 1995).

Li in view of DeNuzzio et al. teaches an apparatus comprising a condensed array addressed device and an optically coupled spectroscope as set forth in item 7 above. Li further teaches that other electronic components can be added to the apparatus including circuitry that allows signal processing (p24, 4$^{th}$ paragraph). However, Li in view of DeNuzzio et al. is silent on an apparatus further comprising memory coupled to the control plurality of sensor elements in the memory.

Ito teaches that a memory for storing data can be provided with a biosensor for storing data (see entire document, particularly Abstract). The data include a time fabricating the biosensor, a lot number, an effective period of the biosensor, biosensor characteristics, measured date, measuring time, and measured results (Abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a memory of Ito, which is configured to store data, coupled to the control circuit of Li in view of DeNuzzio et al. in order to store data associated with plurality of sensor elements. The advantage of storing data, which may include a time fabricating the biosensor, a lot number, an effective period of the biosensor, the biosensor characteristics, measured date, the measuring time, and the measured results, provides the motivation to include a memory of Ito coupled to the control circuit of Li in view of DeNuzzio et al. with a reasonable expectation of success.

***Response to Arguments***

11. Applicant's arguments with respect to claims1-5, 7-16, and 18-21 have been considered but are moot in view of the new ground(s) of rejection set forth in items 7-10 above.

Since the prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- DeNuzzio et al. (U.S.PG Pub. No. US 2004/0040868 A1, Mar. 4, 2004) teaches combination of optical sensing with multiplexed electrochemical sensing using microfabricated sensor arrays (see entire document, particularly p1, paragraph [0001]).
- Sato et al. (U.S. PG Pub No. US 2003/0148361 A1, Aug. 7, 2003) teaches that detection of binding reaction can be performed by detecting combination of both optical and electrochemical signals (see entire document, particularly p1, paragraph [0013]).

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Unsu Jung whose telephone number is 571-272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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